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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,514	02/11/2004	Kerry Zang	073275.0163	5263

5073 7590 12/09/2005

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EXAMINER

AMARELD JR, ROBERT W

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 12/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/777,514		ZANG ET AL.	
	Examiner		Art Unit	
	Robert W. Amareld, Jr.		3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>9/27/05, 2/11/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 7, 17, 18, 20, 21 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Hansson (US Pat# 6503252). Hansson discloses a conical core (21) with a plurality of threads (19) around the conical core to help secure the implant where the conical may have a taper angle (alpha) of 30° (column 3, lines 19-22). The device having maximum outer diameter of 13mm and a threaded portion maximum length of 25mm, which is well within the size range usable within the sinus tarsi of a subtalar joint. The trailing end of the device (18) may have a hole (25) formed in it, which is capable of use with a tool or wire (column 4, lines 18–21). The device of Hansson is formed by milling (milling being essentially the identical to machining) the core portion (21) with a tool (27), (column 4, lines 31-38), and may be formed with a range of crest widths (b1-b7) from 0.2mm-1mm (+/-10%) (column 4, lines 1-5) and a pitch range of 2.6-3.2 (column 3, lines 30-36), these ranges allow for a ratio of crest width to pitch to fall within the range of 0.0625-0.38 which is at least 0.15.

Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Simon (US Pat# 6264677). Simon discloses a conical portion with a plurality of threads which is sized to fit within the sinus tarsi of a subtalar joint as indicated by the size ranges in

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the table (column 3, lines 25-35). The conical portion of the body may have a taper angle of 6-15° or 15-30°, both of which either contain 18° or are approximately 18° and contain portions with a taper between 10° and 30°. The drive head (18) is adapted to receive a socket drive tool (column 3, lines 64-67). In reference to claim 6, the scale drawing in Figure 4 was measured with a ruler, the width of the 2nd crest is ~0.125 inch while the height is ~ 0.3125 inches, which produces a crest height to width ratio of 0.4 which is at least 0.3, additionally the varying height crests in combination with the selected crest width (between 0.08mm-0.3mm, column 3, lines 20-22) produce a wide range of width to height ratios. In reference to claim 8, the threads of the device of Simon may have a pitch of 0.8mm –1.5mm (column 2, lines 64-65) and a width of 0.08mm-0.3mm (column 3, lines 20-22), the pitch is the distance between crests, by subtracting the crest width from the pitch the root width between each thread can be calculated, by performing this calculation with the extremes ranges, the max/min crest width of 0.3 or 0.08mm and the pitch max/min of 1.5 or 0.8 we get the thread root width range of 0.5-1.2mm, which corresponds to range of 0.0196-0.0472 inches for the thread root width, which includes the range of 0.020-0.040 inches of claim 8. An additional conical portion is found on the rounded tip of the drive head (Figure 2, #18) where a cylindrical portion defining the eyelet (20) separates the two conical portions.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simon (US Pat# 6264677) in view of Chauvin (US Pat Appl# 101224044, Pub# US2002/0116066). Simon is explained supra. However, Simon does not disclose a 60°-thread angle, specific thread height or all required pitch ranges. Chauvin teaches a conical/frustoconical profile (paragraph 15, bottom 3 lines) with four slots (10) extending substantially from one end to the other and the conical body has threads with a thread angle of 60° (paragraph 32, bottom 5 lines) where the threads have heights on the order of 0.7 to 0.9mm (paragraph 32) which is approximately 0.032 or 0.041 inches and have a pitch of 1.5-2mm which is approximately 0.090 or 0.100 inches. The device of Chauvin being in the same field of endeavor or the analogous art of surgery, class 606, regarding implantable bone implants for the purpose of repairing damaged structures and/or connecting bony structures. It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the teaching of slots, thread height angle and pitch, as taught by Chauvin, to anchor as per Simon, in order to enhance implant anchoring ability and improve implant retention.

Claims 19, 22, 24-31 rejected under 35 U.S.C. 103(a) as being unpatentable over Simon (US Pat# 6264677) in view of Chauvin (US Pat Appl# 101224044, Pub# US2002/0116066) as applied to claims 10-16 above, and further in view of Hansson (US Pat# 6503252).

Simon and Chauvin disclose the structure of the implant. However Simon and Chauvin do not disclose a specific manufacturing method. Hansson teaches milling (milling being essentially the identical to machining) as a manufacturing method (col. 4, lines 39-43) in the same field of endeavor or the analogous art of surgery, regarding bone implants for the purpose of implanting. It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the teaching of milling the implant, as taught by Hansson, to the implantable device as per Simon and Chauvin, in order to form the implant.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Crombie, US Pat# 5961524- screw; Simon, US Pat# 5951560- orthopedic screw; Grivas, US Pat# 6096081- cortical dowell; Kvarnstrom, US Pat Appl# 09971977, Pub# US 20020052608.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert W. Amareld, Jr. whose telephone number is 571-272-6170. The examiner can normally be reached on M-F 9am -5pm EST.

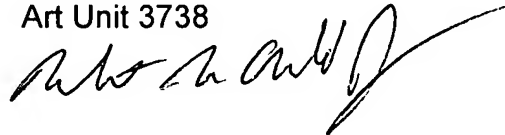
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RWA

Robert W Amareld, Jr.
Examiner
Art Unit 3738



BRIAN E. PELLEGRINO
PRIMARY EXAMINER

